Overview of the FDA-Approved OraQuick® Rapid HIV-1 Antibody Test

CLIAC
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Elliot P. Cowan, Ph.D.

Senior Regulatory Scientist
Office of Blood Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration

Rapid HIV Test Approval

- On November 7, 2002, FDA approved the OraQuick® Rapid HIV-1 Antibody Test as a moderate complexity device under CLIA
- Intended use:
  - To detect antibodies to HIV-1 in fingerstick whole blood specimens
  - A point-of-care test to aid in the diagnosis of infection with HIV-1
  - Suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results

OraQuick® is Approved as a Restricted Device

- Sale is restricted to clinical laboratories
  - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and
  - where there is assurance that operators will receive and use the instructional materials
- Approved for use only by an agent of a clinical laboratory

OraQuick® Restrictions, cont.

- Test subjects must receive the “Subject Information” pamphlet prior to specimen collection and appropriate information when test results are provided
- Not approved for use to screen blood or tissue donors
- Customer letter included with all kits
  - “By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the…restrictions on the sale, distribution, and use of the device…”

Description of the OraQuick® Test

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SUBJECT INFORMATION

What You Should Know About HIV and the OraQuick® Rapid HIV-1 Antibody Test Prior to Being Tested

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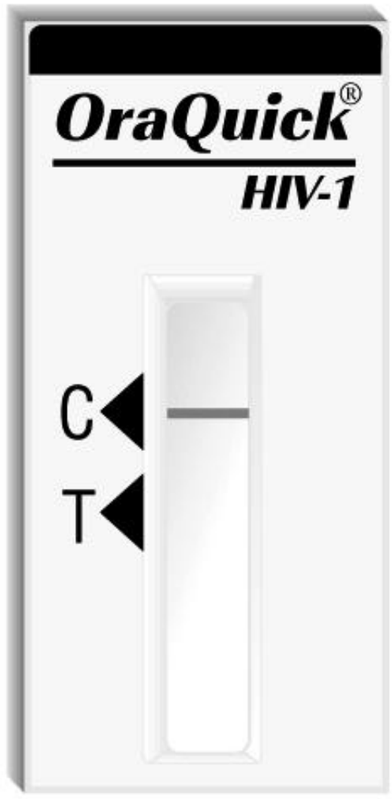
20-60 minutes

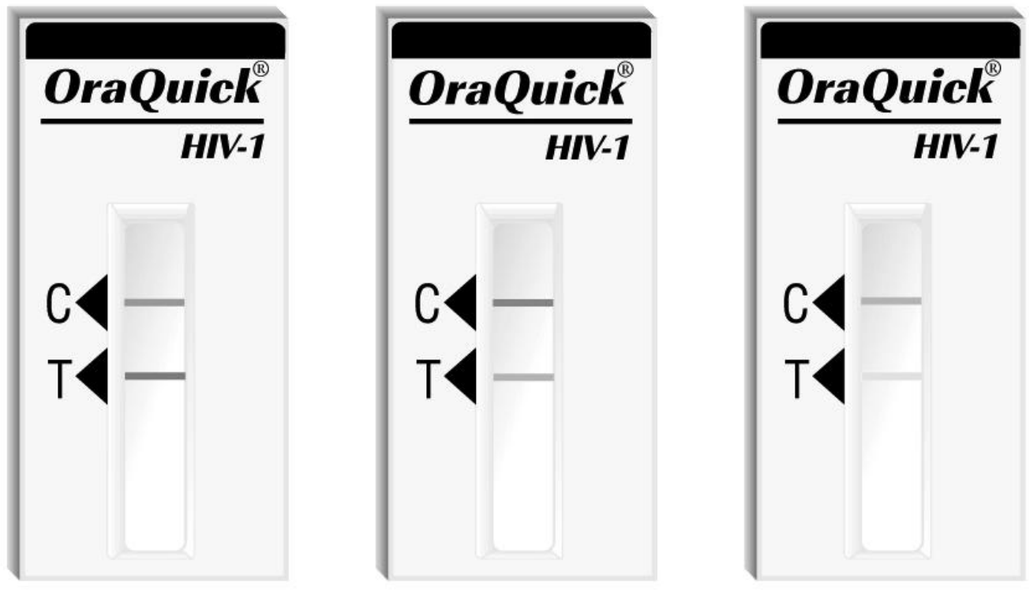
Follow CDC guidelines to inform the test subject of the test result and its interpretation.

OraQuick® Results and Interpretation



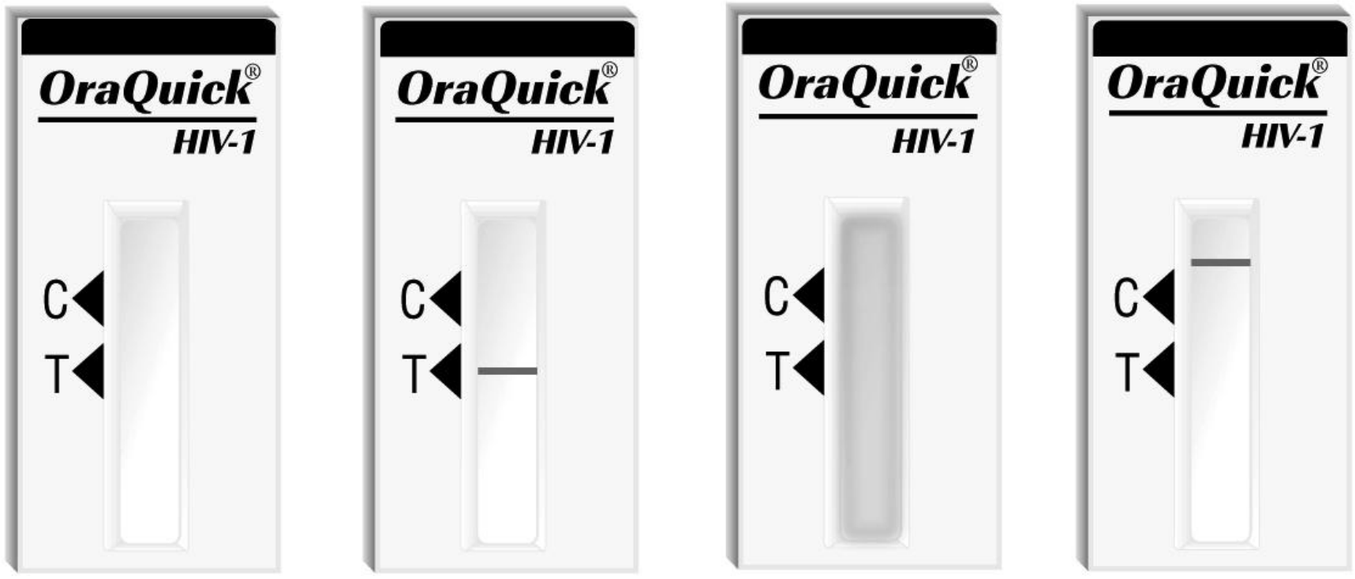
RESULT: **NON-REACTIVE**
INTERP: **NEGATIVE**

OraQuick® Results and Interpretation



RESULT: **REACTIVE**
INTERP: **PRELIM POSITIVE**

OraQuick® Results and Interpretation



INVALID TEST RESULTS

OraQuick® Clinical Trial Data: Sensitivity

Group	Total Samples	OQ Reactive	Licensed EIA RR	WB+
AIDS	40	40	40	40
Known HIV-1+	481	479	481	481
High Risk	625	17	20*	17
TOTAL	1146	536	541	538

*2 specimens negative and 1 indeterminate by WB

SENSITIVITY IN TRIAL: 99.6% (98.5%-99.9%)

OraQuick® Clinical Trial Data: Specificity

Group	Total Samples	OQ NR	Licensed EIA NR	True Neg
Low-Risk	1250[1]	1248	1247	1248
High-Risk	625	608	605	608
TOTAL	1875	1856	1852	1856

*Two specimens from low-risk study gave Reactive results with OQ, RR results with EIA, and positive results with WB.

SPECIFICITY IN TRIAL: 100% (99.7%-100%)

OraQuick® Clinical Trial Data: Reproducibility

- 3 sites, 3 lots, 3 different days, 3 operators/site (9 total)
- Blind-coded panel of 5 contrived whole blood specimens
  - 4 antibody-positive and 1 antibody-negative specimen
- Results
  - 20-minute read time: 404/405 = 99.8%
  - 55-60 minute read time: 405/405 = 100%

OraQuick® CLIA Waiver

- OraQuick® was granted a CLIA waiver on January 31, 2003
- Data submitted in support of waiver
  - At 4 sites, 100 lay users with no laboratory experience tested panels of 6 masked randomized specimens
    - » 2 negative, 2 low positive, 2 high positive
  - No statistically significant difference between lay user results and correct results

OraQuick® CLIA Waiver, cont.

- Package insert for waived device in preparation
  - Will contain details on waiver studies
- Sales and use restrictions remain in place for the waived test
- Quality Assurance program recommendations for rapid HIV tests are being developed by CDC